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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,794	03/20/2006	Terrence C. Dahl	270.PFUS	7159

25000 7590 05/16/2007

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EXAMINER	
PRYOR, ALTON NATHANIEL	
ART UNIT	**PAPER NUMBER**
1616	
MAIL DATE	**DELIVERY MODE**
05/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,794	DAHL ET AL.	
	Examiner	Art Unit	
	Alton N. Pryor	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *59,61-64,66,67,70-88,96 and 98-125* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *59,61-64,66,67,70-88,96 and 98-125* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/22/07;12/08/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, see paper, filed 2/9/07, with respect to the rejection(s) of claim(s) under 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 59,61-64,66,67,70-88,96,98-125 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liotta et al (WO 92/14743; 09/03/92), Becker et al (WO 02/08241 A2; 01/31/02), and Fiske et al (Pharmcokinetics, safety and tolerability of single escalating doses of DMP 266, an HIV non-nucleoside reverse transcriptase inhibitor, in healthy volunteers, Pharmaceutical Research (New York), 1997, vol. 14 no. 11 Suppl. Pp. S609. print.). Liotta teaches a method of treating HIV by administering emtricitabine to a patient infected with HIV. See abstract and claims. Liotta teaches that emtricitabine can be combined with ingredients such as magnesium stearate, corn starch, carriers, and other antiviral compounds prior to administration. See page 52. Liotta also teaches that the composition can exist in the form of a tablet or capsule. Liotta does not teach a method of treating an HIV infected patient comprising administering a composition comprising tenofovir disoproxil fumarate (PMPA) and

Sustiva to the patient. Liotta also does not teach the instant amounts or ratios of actives and instruction information on how to administer the drugs. However, Becker teaches a method of treating an HIV infected patient comprising administering a tenofovir (PMPA) compound including tenofovir disoproxil to the patient. See abstract and claims. Likewise, Fiske teaches a method of administering sustiva (DMP 266) to treat an HIV infected patient. It would have been obvious to one having ordinary skill in the art to add both tenofovir disoproxil fumarate and sustiva to the tablet or capsule containing emtricitabine. One would have been motivated to do this because Liotta encourages the addition of other antiviral compounds to emtricitabine. One having ordinary skill at the time the invention was made would have been expected to determine the optimum amounts or ratios of ingredients to include in the dosage form. One would have been motivated to do this in order to optimize the effectiveness and safety of the dosage form. With respect to instructions on how to use pharmaceuticals, including the one of the instant claims, it is a standard practice to provide a patient consuming the product with instructions on how to administer or use the product in order to arrive at a patient pack or kit. Note the combination of the references cited in this rejection would yield an invention consisting of emtricitabine, disoproxil fumarate and optionally sustiva as the active ingredients. Applicant provides no unexpected or synergistic results for the drug combination.

Response to Applicants' Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 59,62-64, 66,68-90,92,93,96,98,99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (USAN 2005/0197320 or 10/434130; 9/8/05). Chen teaches a method of treating HIV comprising administering to a human inflicted with HIV a composition (tablet, capsule) comprising an imidazole phosphonate compound of formula I. See paragraphs 15-18, 476, 485, 487. Chen teaches combination therapy, which involves adding to the treatment regimen one, or more other active compounds including Sustiva (NNRTI), Emtricitabine, and /or Tenofovir disoproxil. See 507-509, 541-542, 579. Chen teaches the addition of a number of excipients such as magnesium stearate (glidant), cellulose, calcium carbonate, and starch to the composition. See paragraphs 475,485, and 487. Chen teaches administering the actives to a human in need thereof on a one time per day dosage basis. See 492 and 504. Chen does not teach the a) combination therapeutic treatment comprising all 4 actives, b) instant amounts and ratios of actives and c) a patient package comprising the actives with attached instructions for using. However, one having ordinary skill in the art would have been motivated to do this since Chen suggests HIV treatment regimens can include the simultaneous or sequential

administration of one or more actives to an HIV infected patient. See USAN 2005/0197320 paragraphs 507-509. With respect to the amounts and ratios of ingredients an artisan would have been motivated to optimize the ratios and amounts. An artisan would have been especially motivated to do this because drugs are known to be highly toxic, i.e., killing healthy cells. There is nothing unobvious in having drugs in a packs with instructions. In fact, in the medical industry drugs always come with instructions as how to use them.

Applicants argue that the claims as amended, "consisting of" tenofovir disoproxil fumarate, emtricitabine and optionally sustiva as actives overcome the art rejection of Chen since Chen requires a sulfur substituted imidazole phosphonate compound.

Examiner agrees with Applicants' argument and withdraws the rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 59, 62-64,66,68-90,92,93,96,98,99 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8,10,15-20,22-26,42-55,58 of copending Application No. 10/757141. Although the conflicting claims are not identical, they are not patentably distinct from each other because USAN '141 claims an invention for treating HIV comprising administering to a human inflicted with HIV a composition (tablet, capsule) comprising Sustiva (NNRTI), Emtricitabine, and /or Tenofovir disoproxil. USAN '141 claims the actives can be contained in a patient pack with instructions attached for use, and the amounts / ratios of actives claimed in USAN '141 overlap the instant amounts / ratios of actives. USAN '141 claims the addition of a number of excipients such as magnesium stearate (glidant), cellulose, calcium carbonate, and starch to the composition. USAN '141 claims administering the actives to a human in need thereof on a one time per day dosage basis. USAN '141 inherently claims the instant invention. However instant invention is of a narrower scope than USAN '141 in that instant invention unlike USAN '141 does not make claim to preventing the symptoms or effects of an HIV infected subject.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant has abandoned application no. 10/757141. Therefore, Examiner withdraws the obviousness-type double patenting rejection over '141.

Claim Objection / Election Status

In office action mailed 09/21/06 claims 60,61,67, and 97 were objected to and considered allowable. However, due to the rejection cited above over Liotta et al, Becker et al, and Fiske et al, the claims are no longer considered allowable. The elected combination of emtricitabine, disoproxil fumarate and sustiva is not allowable. See art rejection.

Applicants' concerns

Applicants are concerned that USANs 11/453,122 and 11/452472 may initiate provisional double patenting rejections. Examiner reminds applicant that instant application has the earliest filing date. Therefore, no terminal disclaimer will be necessary in instant application. However, in later filed USANs '122 and 472 double patenting rejections may be issued in an office action and a terminal disclaimer may be required to overcome those rejections.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alton Pryor
Primary Examiner
A.U. 1616